

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1470

of 5 September 2022

concerning the authorisation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* CBS 139997 and alpha-galactosidase produced by *Aspergillus tubingensis* ATCC SD 6740 as a feed additive for chickens for fattening, chickens reared for laying, minor poultry species for fattening and reared for laying, and ornamental birds (holder of the authorisation Industrial Técnica Pecuaria S.A.)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* CBS 139997 and alpha-galactosidase produced by *Aspergillus tubingensis* ATCC SD 6740. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of the preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* CBS 139997 and alpha-galactosidase produced by *Aspergillus tubingensis* ATCC SD 6740 as feed additive for chickens for fattening, chickens reared for laying, minor poultry species for fattening and reared for laying, and ornamental birds, to be classified in the additive category 'zootechnical additives' and the functional group 'digestibility enhancers'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 19 March 2020 ⁽²⁾ and 10 November 2021 ⁽³⁾ that, under the proposed conditions of use, the preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* CBS 139997 and alpha-galactosidase produced by *Aspergillus tubingensis* ATCC SD 6740 does not have an adverse effect on animal health, consumer safety or the environment. Due to the lack of data, the Authority couldn't conclude on the skin or eye irritation potential of the preparation nor on its skin sensitisation potential. Owing to the proteinaceous nature of the preparation, it should be regarded as a potential respiratory sensitiser, but the exposure is presumed to be limited due to the low dusting potential. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive.
- (5) The Authority further concluded that the preparation has a potential to be efficacious as a zootechnical additive for the requested target species. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (6) The assessment of the preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* CBS 139997 and alpha-galactosidase produced by *Aspergillus tubingensis* ATCC SD 6740 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2020;18(4):6086.

⁽³⁾ EFSA Journal 2021;19(12):6981.

- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 5 September 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Units of activity/kg of complete feedingstuff with a moisture content of 12 %			

Category of zootechnical additives. Functional group: digestibility enhancers

4a33	Industrial Técnica Pecuaria S.A	Endo-1,4-beta-xylanase and alpha-galactosidase	<i>Additive composition</i> Preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by <i>Trichoderma longibrachiatum</i> CBS 139997 and alpha-galactosidase (EC, 3.2.1.22) produced by <i>Aspergillus tubingensis</i> ATCC SD 6740 having a minimum enzyme activity of: 50 AXC ⁽¹⁾ /g of additive and 40 GALU/g ⁽²⁾ of additive	Chickens for fattening, Chickens reared for laying Minor poultry species for fattening and reared for laying Ornamental birds	-	18 AXC 14 GALU	-	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin, eyes and breathing protection.	26.9.2032
			Solid form						
			<i>Characterisation of active substance</i> Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by <i>Trichoderma longibrachiatum</i> CBS 139997 and a-galactosidase (EC 3.2.1.22) produced by <i>Aspergillus tubingensis</i> ATCC SD 6740						
			<i>Analytical method</i> ⁽³⁾ For the quantification of endo-1,4-beta-xylanase in the feed additive, premixtures and feedingstuffs:						

			<ul style="list-style-type: none"> — colorimetric method based enzymatic reaction of endo-1,4-beta-xylanase i) on a wheat arabinoxylan substrate (for the feed additive and premixtures) and ii) on an azo-xylan substrate (for feedingstuffs). <p>For the quantification of alpha-galactosidase in the feed additive, premixtures and feedingstuffs:</p> <ul style="list-style-type: none"> — colorimetric method based on the enzymatic reaction of alpha-galactosidase on the para-nitrophenyl-alpha-D-galactopyranoside substrate 						
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⁽¹⁾ 1Unit of endo-1,4-beta-xylanase activity (AXC) is the amount of enzyme, which liberates 0,058 micromoles per minute of reducing sugars, expressed as xylose equivalents, from a wheat arabinoxylan substrate at pH 4,7 and 30 °C.

⁽²⁾ 1Unit of alpha-galactosidase activity (GALU) is defined as the amount of enzyme which degrades one micromole per minute of para-nitrophenyl-alpha-D-galactopyranoside at pH 5,5 and 37 °C.

⁽³⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en